

# COLLINS, McDONALD & GANN, P.C.

Attorneys At Law

MAY 10 2004

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April 27, 2004

Via Certified Mail Return Receipt Requested

Office of Nutritional Products, Labeling  
and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

NOTIFICATION OF STATEMENT  
OF NUTRITIONAL SUPPORT

On behalf of Instone, LLC, Irvine, California 92612, the undersigned files this notification pursuant to section 403(r)(6) of the Federal Food Drug and Cosmetic Act and 21 C.F.R. § 101.93. The certification required by 21 C.F.R. § 101.93(a)(3) is also attached.

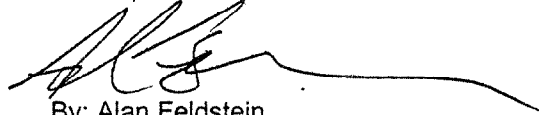
Brand Name: Leanfire™

Statements of Nutritional Support:

- Keeps your metabolism optimized even when operating on reduce calories
- Increases energy levels to support an active and healthy lifestyle

The above label also includes the disclaimer statement required under 21 C.F.R. §§101.93(b) and (c).

Collins, McDonald & Gann



By: Alan Feldstein  
Of Counsel to the Firm

Attachment – Certification

cc: Instone, LLC.

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**INSTONE** ✦

T 949.854.1600 F 949.854.1608  
5251 CALIFORNIA, SUITE 150  
IRVINE, CA 92612  
[WWW.INSTONENUTRITION.COM](http://WWW.INSTONENUTRITION.COM)

**21 C.F.R. § 101.93(a)(3) Certification**

To the best of my knowledge and based on information and belief at the time of executing this notice I certify that the information contained in the preceding section 403(r)(6) notice for LEANFIRE™ dietary supplement is complete and accurate and that Instone, LLC has substantiation that the statement is truthful and not misleading.



Alan Roberts, M.Sc.  
Senior Director of Product Development  
And Regulatory Affairs